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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR 09/920,467 08/01/2001 Michael L. Blomquist 9015.135USI1 5608 23552 01/19/2006 **EXAMINER** 7590 MERCHANT & GOULD PC KOPPIKAR, VIVEK D P.O. BOX 2903 ART UNIT PAPER NUMBER MINNEAPOLIS, MN 55402-0903 3626

DATE MAILED: 01/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)
	09/920,467	BLOMQUIST, MICHAEL L.
Office Action Summary	Examiner	Art Unit
	Vivek D. Koppikar	3626
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply		
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailling date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).		
Status		
1) Responsive to communication(s) filed on 8/1/01.		
2a) ☐ This action is FINAL . 2b) ☑ This	action is non-final.	
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.		
Disposition of Claims		
4) Claim(s) 1-20 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) 1-20 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement.		
Application Papers		
9) ☐ The specification is objected to by the Examiner. 10) ☑ The drawing(s) filed on <u>01 August 2001</u> is/are: a) ☑ accepted or b) ☐ objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.		
Priority under 35 U.S.C. § 119		
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some c) None of: Certified copies of the priority documents have been received. Certified copies of the priority documents have been received in Application No Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 		
Attachment(s) 1) ☑ Notice of References Cited (PTO-892) 2) ☑ Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) ☑ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 4/23/03 &6/14/04.	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:	

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DETAILED ACTION

Status of the Application

1. Claims 1-20 have been examined in this application. The Information Disclosure Statement (IDS) statements filed on April 23, 2003 and June 14, 2004 have also been acknowledged. This application is a continuation-in-part (CIP) of application 09/631,000.

Double Patenting

2. Claims 1-20 of this application conflict with claims 1-20 of Application No.09/631,000.

37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

Claim Rejections - 35 USC § 103

- 3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 4. Claims 1-3 and 6-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent Number 5,788,669 to Peterson in view of US Patent Number 5,713,856 to Eggers.
- (A) As per claim 1, Petersen discloses a method for creating a library pump data on a computer having a database (Petersen: Abstract), the pump data being organized into sets of

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program data, each set of program data being available for batch downloading to a medical pump and including data items for controlling operation of the medical pump, the method comprising:

the plurality of data items forming a set of program data (Peterson: Col. 4, Ln. 10-18 and Ln. 36-53);

Peterson does not explicitly disclose at least some of the data items establishing parameters for controlling operation of a medical pump entering a plurality of data items into a database on the computer.

However, Eggers discloses at least some of the data items establishing parameters for controlling operating of a medical pump (i.e. drug libraries customized for each user) (Eggers: Col. 10, Ln. 62-Col. 11, Ln. 45) entering a plurality of data into a database on the computer, and assigning at least one data key to the set of program data, the data key identifying the set of program data (i.e. drug libraries customized for each user) (Col. 10, Ln. 62-Col. 11, Ln. 45). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have included at least some of the data items establishing parameters for controlling operation of a medical pump, entering a plurality of data items into a database on the computer disclosed by Eggers within the system taught by Peterson for the motivation of downloading complicated drug delivery profiles to the system (Eggers: Col. 2, Ln. 3-10 and Col. 11, Ln. 14-20).

Peterson and Eggers do not explicitly disclose assigning at least one data key to the set of program data, the data key identifying the set of program data; however, the examiner takes

Official Notice that it was well known in the database arts to assign identifies to data sets. The purpose of using identifiers was to locate the particular data that is to be utilized by a user or program. It would have been obvious to one of ordinary skill in the art at the time of the

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invention to have included the step of assigning at least one data key to the set of program data, the data key identifying the set of program data within Peterson and Eggers for the motivation stated above.

(B) As per claim 2, Peterson does not explicitly disclose the method of claim 1 wherein the acts of: entering a plurality of data items into a database includes entering the plurality of data items into a program data record in the database.

However, Eggers discloses entering a plurality of data items into a database includes entering the plurality of data items into a program data record in the database (i.e. drug library (Col. 2, lines 3-10 and col. 11, lines 14-20). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include entering a plurality of data items into a database includes entering the plurality of data items into a program data record in the database as disclosed by Eggers within the Peterson system for the motivation of downloading complicated drug delivery profiles to the system (col. 2, lines 3-10 and col. 11, lines 14-20). Peterson and Eggers do not explicitly disclose assigning at least one data key to the set of program data includes entering the data key into a data key record and linking the data key record to the program data record. However, the Examiner takes official notice that it was well known in the database arts to assign identifiers to data sets and linking data key records to application programs. The purpose of using identifiers was to locate the particular data that is to be utilized by a user or program. It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include assigning at least one data key to the set of program data includes entering the data key into a data key record and linking the data key record to the program data record within Peterson and Eggers for the motivation stated above.

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- (C) As to claim 3, Peterson does not explicitly disclose the method of claim 2 wherein further including entering an identification code selected from the group consisting essentially of a patient I.D., a therapy I.D., and a fluid I.D., wherein the patient I.D. is a code identifying a patient, the therapy I.D. is a code identifying a therapy administered using a medical pump, and the fluid I.D. is a code identifying a fluid that is administered using a medical pump. However, Eggers discloses further including entering an identification code selected from the group consisting essentially of a patient I.D., a therapy I.D., and a fluid I.D., wherein the patient I.D. is a code identifying a patient, the therapy I.D. is a code identifying a therapy administered using a medical pump, and the fluid I.D. is a code identifying a fluid that is administered using a medical pump (Col. 10, Ln. 62 - Col. 11, Ln. 7). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include entering an identification code selected from the group consisting essentially of a patient I.D., a therapy I.D., and a fluid I.D., wherein the patient I.D. is a code identifying a patient, the therapy I.D. is a code identifying a therapy administered using a medical pump, and the fluid I.D. is a code identifying a fluid that is administered using a medical pump as disclosed by Eggers within the Peterson system for the motivation of downloading complicated drug delivery profiles to the system (Col. 2, Ln. 3-10 and col. 11, Ln. 14-20).
- (D) As per claim 6, Peterson in view of Eggers disclose a computer storage medium which contains a library of pump data, the computer storage medium is created by the method set forth in Claim 1.
- (E) As per claim 7, Peterson an apparatus for maintaining a library of program data for medical pumps, the apparatus comprising: memory loaded with a database, the database

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including a plurality of program data records and a plurality of data key records, each program data record containing a set of program data items (Peterson: Col. 4, Ln. 10-18 and Ln. 36-53) Peterson does not teach that at least some of the program data items included in the database for controlling operation of a medical pump, each data key record containing a data key and each data key identifying one of the data program records; however this feature is well known in the art as evidenced by Eggers discloses at least some of the data items establishing parameters for controlling operating of a medical pump (i.e. drug libraries customized for each user) (Eggers: Col. 10, Ln. 62-Col. 11, Ln. 45) entering a plurality of data into a database on the computer, and assigning at least one data key to the set of program data, the data key identifying the set of program data (i.e. drug libraries customized for each user) (Col. 10, Ln. 62-Col. 11, Ln. 45). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have included at least some of the data items establishing parameters for controlling operation of a medical pump, entering a plurality of data items into a database on the computer disclosed by Eggers within the system taught by Peterson for the motivation of downloading complicated drug delivery profiles to the system (Eggers: Col. 2, Ln. 3-10 and Col. 11, Ln. 14-20).

Peterson and Eggers do not explicitly disclose a database management system programmed to link a data key to a set of program data; however, the examiner takes Official Notice that it was well known in the database arts to assign identifies to data sets. The purpose of using identifiers was to locate the particular data that is to be utilized by a user or program. It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the step of assigning at least one data key to the set of program data, the data key identifying the set of program data within Peterson and Eggers for the motivation stated above.

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(F) As per claim 8, the system of Peterson in view of Eggers does not comprise a scanner in data communication with the database management system, the database management system being further programmed to receive a code scanned by the scanner, save the code in a data key record, and link the code to a set of program data, the code being a data key. However the examine takes Official Notice that it was well known in the database art to place a scanner in data communication with the database management system, the database management system being further programmed to receive a code scanned by the scanner, save the code in a data key record, and link the code to a set of program data, the code being a data key. It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the above mentioned step within Peterson and Eggers for the motivation stated above.

- (G) As per claim 9, the apparatus of Peterson in view of Eggers further includes a means whereby the medical pump stores a set of program data, the database management system being further programmed to receive the set of program data from the medical pump and save the set of program data as a record in the database (Peterson: Col. 2, Ln. 6-26).
- (H) As per claim 10, Peterson teaches an apparatus for batch programming a medical pump, the apparatus comprising: memory loaded with a database (Peterson: Col. 2, Ln. 6-25), the database including a plurality of program data records and a plurality of data key records, each program data record containing a set of program data items (Col. 2, Ln. 6-24 and Col. 6, Ln. 9-17). a data output configured for data communication with a programmable medical pump(Peterson: Figure 2 and Col. 3, Ln. 66-Col. 4, Ln. 12); and Peterson teaches a processor in electrical communication with the memory and the data output (Peterson: Col. 3, Ln. 66-Col. 4,

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Ln. 12), the processor configured to retrieve a set of program data from the database and batch download the set of program data to the medical pump (Peterson: Col. 4, Ln. 2-12).

Peterson does not teach that at least some of the program data items included in the database for controlling operation of a medical pump, each data key record containing a data key and each data key identifying one of the data program records; however, Eggers discloses at least some of the data items establishing parameters for controlling operating of a medical pump (i.e. drug libraries customized for each user) (Eggers: Col. 10, Ln. 62-Col. 11, Ln. 45) entering a plurality of data into a database on the computer, and assigning at least one data key to the set of program data, the data key identifying the set of program data (i.e. drug libraries customized for each user) (Col. 10, Ln. 62-Col. 11, Ln. 45).

At the time of the invention, it would have been obvious for one of ordinary skill in the art to have included at least some of the data items establishing parameters for controlling operation of a medical pump, entering a plurality of data items into a database on the computer disclosed by Eggers within the system taught by Peterson for the motivation of downloading complicated drug delivery profiles to the system (Eggers: Col. 2, Ln. 3-10 and Col. 11, Ln. 14-20). Peterson and Eggers do not explicitly disclose assigning at least one data key to the set of program data, the data key identifying the set of program data; however, the examiner takes Official Notice that it was well known in the database arts to assign identifies to data sets. The purpose of using identifiers was to locate the particular data that is to be utilized by a user or program. It would have been obvious to one of ordinary skill in the art at the time of the

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invention to have included the step of assigning at least one data key to the set of program data, the data key identifying the set of program data within Peterson and Eggers for the motivation stated above.

- (I) As per claim 11, the apparatus of Peterson in view of Eggers comprises a serial communication cable connected to the data output (Peterson: Col. 3, Ln. 65-Col. 4, Ln. 12).
- (J) As per claim 12, the apparatus of Peterson in view of Eggers further comprises a medical pump in data communication with the data output (Peterson: Col. 3, Ln. 65-Col. 4, Ln. 12).
- (J) As per claim 13, the apparatus of Peterson in view of Eggers teaches each data key record includes first and second fields, the first field for storing an identification code and the second field from storing a name in prose (Eggers: Col. 10, Ln. 62 Col. 11, Ln. 7).
- (K) As per claim 14, in the apparatus of Peterson in view of Eggers each data key record includes fields for a patient I.D., a therapy I.D., and a fluid I.D (Eggers: Col. 10, Ln. 62-Col. 11, Ln. 7).
- (L) As per claim 15, in the apparatus of Peterson in view of Eggers the processor is programmed to generate a user interface, the user interface including a plurality of graphical fields for program data (Eggers: Figure 21 and Col. 16, Ln. 39-45).
- (M) As per claim 16, Peterson teaches a method for batch programming a medical pump (Peterson: Abstract), the method comprising: selecting a set of program data (Peterson: Col. 2, Ln. 4-26 and batch downloading the set of program data to the medical pump, wherein the set of program data is downloaded to the medical pump without intervening action by a user after the first data item is downloaded to the computer (Col. 5, Ln. 31-44). Peterson does not teach that a set

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of program data including data items for controlling operation of a medical pump.

However, Eggers discloses at least some of the data items establishing parameters for controlling operating of a medical pump (i.e. drug libraries customized for each user) (Eggers: Col. 10, Ln. 62-Col. 11, Ln. 45) entering a plurality of data into a database on the computer, and assigning at least one data key to the set of program data, the data key identifying the set of program data (i.e. drug libraries customized for each user) (Col. 10, Ln. 62-Col. 11, Ln. 45). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have included at least some of the data items establishing parameters for controlling operation of a medical pump, entering a plurality of data items into a database on the computer disclosed by Eggers within the system taught by Peterson for the motivation of downloading complicated drug delivery profiles to the system (Eggers: Col. 2, Ln. 3-10 and Col. 11, Ln. 14-20).

- (N) As per claim 17, the method of Peterson in view of Eggers teaches an information management system is loaded on a computer and the information management system includes a database storing a plurality of data keys and a plurality of program data sets, and wherein the act of selecting a set of program data comprises: entering a data key into the information management system; referencing the data key to a program data set; and retrieving the referenced program data set from the database (Eggers: Col. 10, Ln. 62-Col. 11, Ln. 45).
- (O) As per claim 19, the method of Peterson in view of Eggers teaches an information management system is loaded on a computer and the information management system includes a database storing a plurality of data keys and a plurality of program data sets and the act of batch downloading the set of program data includes downloading the set of program data from the computer to the medical pump, the method further comprising: uploading the set of program data

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from the medical pump to the computer after it is downloaded to the medical pump (Eggers: Col. 5, Ln. 6-17 and Ln. 46-54)); comparing the set of program data that was download to the medical pump to the set of program data that was uploaded from the medical pump (Eggers: Col. 5, Ln. 6-17); and generating an error if the set of program data that was downloaded from the medical pump is not identical to the program data that was uploaded from the medical pump (Eggers: Col. 5, Ln. 14-17).

- (P) As per claim 20, the method of Peterson and Eggers includes a propagated signal on a carrier detectable by a computing system and encoding a set of program data for controlling operation of a medical pump, the propagated signal being encoded according to the method of Claim 16 (Peterson: Col. 5, Ln. 38-45).
- 5. Claim 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peterson in view Eggers as applied to claim 3 above, and in further in view of "Acute Health Solutions"
- (A) As to claim 4, Peterson does not explicitly disclose the method of claim 3 wherein the computer is in data communication with a scanner, the method further comprising: scanning a bar code with the scanner; and entering the bar code into the computer, wherein the act of assigning at least one data key to the set of program data includes assigning the bar code to the set of program data.

However, "Acute Health Solutions" discloses wherein the computer is in data communication with a scanner, the method further comprising: scanning a bar code with the scanner; and entering the bar code into the computer, wherein the act of assigning at least one data key to the set of program data includes assigning the bar code to the set of program data (see abstract and page 2, paragraph 3). It would have been obvious to one of ordinary skill in the art

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at the time of Applicant's invention to include wherein the computer is in data communication with a scanner, the method further comprising: scanning a bar code with the scanner; and entering the bar code into the computer, wherein the act of assigning at least one data key to the set of program data includes assigning the bar code to the set of program data as disclosed by "Acute Health Solutions" within the Peterson system for the motivation of insure association of

the drug and concentration with a pump rate and an infusion amount (Abstract).

- (B) As per claim 5, Peterson does not explicitly disclose the method of claim 3 wherein the computer is in data communication with a medical pump, the method further comprising uploading a set of program data items from the pump. However, "Acute Health Solutions" discloses wherein the computer is in data communication with a medical pump, the method further comprising uploading a set of program data items from the pump (see abstract and page 2). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include wherein the computer is in data communication with a medical pump, the method further comprising uploading a set of program data items from the pump as disclosed by "Acute Health Solutions" within the Peterson system for the motivation of insure association of the drug and concentration with a pump rate and an infusion amount (Abstract).
- 6. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Peterson in view of Eggers as applied to claim 3 above, and in further in view of "Acute Health Solutions"
- (A) As per claim 18, the method of Peterson in view of Eggers does not disclose that the act of entering a day key includes scanning a bar code, however, this feature is well known in the art as evidenced by Acute Health Solutions (Abstract and Page 2). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include wherein the computer is

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in data communication with a medical pump, the method further comprising uploading a set of program data items from the pump as disclosed by "Acute Health Solutions" within the Peterson system for the motivation of insure association of the drug and concentration with a pump rate and an infusion amount (Acute Health Solutions: Abstract)

Conclusion

- 7. Any inquire concerning this communication or earlier communications from the examiner should be directed to Vivek Koppikar, whose telephone number is (571) 272-5109. The examiner can normally be reached from Monday to Friday between 8 AM and 4:30 PM. If any attempt to reach the examiner by telephone is unsuccessful, the examiner's supervisor, Joseph Thomas, can be reached at (571) 272-6776. The fax telephone number for this group is (703) 305-7687 (for official communications including After Final communications labeled "Box AF").
- 8. Another resource that is available to applicants is the Patent Application Information Retrieval (PAIR). Information regarding the status of an application can be obtained from the (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAX. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, please feel free to contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sincerely,

Vivek Koppikar

11/8/2005